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Chapter 1 – Summary Information

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K003112.

1. Submitter name, address, contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(716) 453-4469

Contact Person: Susan Werner

Date 510(k) prepared: October 2, 2000

2. Device Name

Trade or Proprietary Name: *Vitros* Immunodiagnostic Products Anti-HBs Controls
Common Name: Anti-HBs controls
Classification Name: 21CFR 862.1660 Quality Control Material (Assayed and Unassayed).

3. Predicate Device

The *Vitros* Immunodiagnostic Products Anti-HBs Controls are substantially equivalent to Blackhawk BioSystems, Inc. VIROTROL® II (BK960085-0).

4. Device Description

The *Vitros* Immunodiagnostic System uses luminescence as the signal in the qualitative determination of anti-HBs in human serum. Coated microwells are used as the solid phase separation system.

The system is comprised of three main elements:

1. The *Vitros* Immunodiagnostic Products range of products, in this case *Vitros* Immunodiagnostic Products Anti-HBs Reagent Pack and *Vitros* Immunodiagnostic Products Calibrators which are combined by the *Vitros* Immunodiagnostic System to perform a *Vitros* assay. The *Vitros* Immunodiagnostic Products Anti-HBs Reagent Pack and Calibrators have been approved for sale by Premarket Approval application P000014.

2. The *Vitros* Immunodiagnostic System - instrumentation, which provides automated use of the immunoassay kits. The *Vitros* Immunodiagnostic System was cleared for market by a separate 510(k) pre-market notification (K962919).

3. Common reagents used by the *Vitros* System in each assay. The *Vitros* Immunodiagnostic Products Signal Reagent and *Vitros* Immunodiagnostic Products Universal Wash Reagent were cleared as part of the *Vitros* Immunodiagnostic Products Total T3 510(k) pre-market notification (K964310).

The *Vitros* System and common reagents are dedicated specifically only for use with the *Vitros* Immunodiagnostic Products range of immunoassay products.

5. Device Intended Use

The *Vitros* Anti-HBs Controls are intended for use in monitoring the performance of the *Vitros* Immunodiagnostic System when used for the qualitative *in vitro* determination of total antibody to hepatitis B surface antigen (anti-HBs) in human serum using the *Vitros* ECi Immunodiagnostic System.

6. Comparison to Predicate Device

The *Vitros* Immunodiagnostic Products Anti-HBs Controls are substantially equivalent to Blackhawk BioSystems, Inc. VIROTROL® II (BK960085-0).

Table 1 lists the similarities and differences of the device characteristics between the *Vitros* Anti-HBs Controls and the predicate device.

Table 1 Characteristics of the Controls

Characteristics	New Device	Predicate Device
Intended use	For use in monitoring the performance of the *Vitros* Immunodiagnostic System when used for the qualitative *in vitro* determination of total antibody to hepatitis B surface antigen (anti-HBs) in human serum using the *Vitros* ECi Immunodiagnostic System.	VIROTROL II is an unassayed positive control specimen prepared from processed human plasma and serum and is intended for use with in vitro assay procedures for determination of antibodies to Hepatitis B surface Antigen (anti-HBs) and qualitative assay procedures for determination of antibodies to Hepatitis A Virus (anti-HAV). VIROTROL reagents are intended to provide a means of estimating precision and have the potential for detecting systematic deviations from specific laboratory testing procedures.

Table 1 (continued)

Characteristics	New Device	Predicate Device
Matrix of controls	Human serum with added constituents of human origin and antimicrobial agents	Human serum with added constituents of human origin and stabilizers
Control levels	Positive and negative	Positive
Expected values	Each control has quoted, a mean value derived from a minimum of 10 assays and a standard deviation anticipated for single determinations of each control in a number of different laboratories using different reagent batches. Values are lot specific.	As stated in the package insert, since VIROTROL reagents do not have assigned values, it is recommended that each laboratory validate the use of each lot of VIROTROL II with each specific assay system prior to its routine use in the laboratory.

7. Conclusions

The information presented in the pre-market notification demonstrates that the *Vitros* Anti-HBs Controls are substantially equivalent to the predicate device Blackhawk BioSystems, Inc. VIROTROL® II which was cleared by FDA (BK960085-0).

The information presented in the premarket notification provide a reasonable assurance that the *Vitros* Anti-HBs Controls are safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Susan Werner
Regulatory Affairs Associate
Ortho-Clinical Diagnostics, Inc.
Regulatory Affairs MC00882
100 Indigo Creek Drive
Rochester, New York 14626-5101

Re: K003112
Trade Name: Vitros Immunodiagnostic Products Anti-HBs Controls
Regulatory Class: I
Product Code: JJX, MJY, MJX
Dated: October 3, 2000
Received: October 4, 2000

Dear Ms. Werner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Intended Use

510(k) Number (if known): K003112

Device Name: *Vitros* Immunodiagnostic Products Anti-HBs Controls

Indications for Use: For use in monitoring the performance of the *Vitros* Immunodiagnostic System when used for the qualitative *in vitro* determination of total antibody to hepatitis B surface antigen (anti-HBs) in human serum using the *Vitros* ECi Immunodiagnostic System.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Woody Dubois
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003112